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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,563	07/16/2003	Satoshi Kidooka	P23565	7116

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GREENBLUM & BERNSTEIN, P.L.C.
1950 ROLAND CLARKE PLACE
RESTON, VA 20191

EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/619,563

Applicant(s)

KIDOOKA, SATOSHI

Examiner

Michael Peffley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 22, 2006 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ouchi (2002/0123667) in view of Rydell (5,035,696) and further in view of the teaching of Weaver et al (5,536,248).

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Ouchi discloses a bipolar treatment tool for an endoscope substantially as set forth in the instant application claims. It includes a flexible insulating tube (102) made of PTFE (col. 3, line 13), an end effector (110,112) attached to the end of the tube and a pair of conductive wires (122,124) extending through the tube and coupled to the end

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effector to provide bipolar energy to the individual jaws. The examiner maintains that the use of any well known insulating material, including a silicone resin, for making the flexible tube is deemed an obvious design consideration for one of ordinary skill in the art. Slater et al also disclose a proximal operating portion (Figure 1) for actuating the pair of conductive wires to operate the end effector. The only features not taught by Ouchi is the provision of two generally circular channels in the insulating tube through which the wires are individually passed. Rather, Ouchi provides a single channel and passes both wires through the single channel, each wire provided with its own individual insulation sheath.

Rydell also discloses a flexible, bipolar tool for an endoscope. In particular, Rydell teaches that the two conductive wires (24,26) may be individually insulated and passed through a lumen in the flexible insulating tube (see Figure 1). Alternatively, Rydell also teaches that the wires may be uninsulated and the flexible insulating sheath may be provided with two channels for housing the wires individually and obviate the need for an insulation coating on the wires (see Figure 5 and col. 5, lines 10-19). The Rydell lumens are semi-circular in shape. The examiner maintains that the use of any shaped lumen in a catheter device would be an obvious design consideration for one of ordinary skill in the art.

In support of this assertion, Weaver et al disclose another flexible electrosurgical tool for an endoscope very much like the Rydell device. In particular, Weaver et al provide lumens in the flexible body for the passage of various instruments and devices, including electrode leads. Of particular note, Weaver et al teach of the well-known use

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of variously shaped lumens for providing advantageous characteristics, such as diminished cross sectional area, for the flexible member. Figures 12 and 12a of the Weaver et al device show the use of circular-shaped lumens, and Figures 19-24 show various other configurations including combinations of circular and semi-circular shaped lumens to maximize lumen surface area. In column 10, lines 18-35, Weaver et al specifically disclose that the various alternative lumen shapes are deemed obvious alternatives.

To have provided the Ouchi flexible tube with two channels for providing the individual conductive wires and obviating the need for insulation coatings on the individual wires would have been an obvious alternative arrangement for one of ordinary skill in the art, particularly since Rydell teach that providing two channels in an insulating tube is a known alternative to insulated wires being passed through a single lumen in an insulating tube. To have further provided the two channels as two circular lumens to more fittingly receive the leads would have been an obvious design consideration for one of ordinary skill in the art in view of the Weaver et al patent which teaches that such alternative lumen shapes are generally well known and obvious alternatives.

Claims 1-7 and 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slater et al (5,482,054) in view of Rydell (5,035,696) and further in view of the teaching of Weaver et al (5,536,248).

Slater et al discloses a bipolar treatment tool for an endoscope substantially as set forth in the instant application claims. It includes a flexible insulating tube (50,300)

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made of poly-ethylene (col. 5, line 42), an end effector (18) attached to the end of the tube and a pair of conductive wires (60) extending through the tube and coupled to the end effector to provide bipolar energy to the individual jaws. The examiner maintains that the use of any well known insulating material, including a silicone resin, for making the flexible tube is deemed an obvious design consideration for one of ordinary skill in the art. Slater et al also disclose the particular jaw and clevis assembly including a pair of pins (134,136) spaced apart from each other, each pin supporting a jaw. Ouchi also disclose a proximal operating portion (not shown) for actuating the pair of conductive wires to operate the end effector (col. 4, lines 37+). The only features not taught by Ouchi is the provision of two generally circular channels in the insulating tube through which the wires are individually passed. Rather, Ouchi provides a single channel and passes both wires through the single channel, each wire provided with its own individual insulation sheath.

Rydell also discloses a flexible, bipolar tool for an endoscope. In particular, Rydell teaches that the two conductive wires (24,26) may be individually insulated and passed through a lumen in the flexible insulating tube (see Figure 1). Alternatively, Rydell also teaches that the wires may be uninsulated and the flexible insulating sheath may be provided with two channels for housing the wires individually and obviate the need for an insulation coating on the wires (see Figure 5 and col. 5, lines 10-19). The Rydell lumens are semi-circular in shape. The examiner maintains that the use of any shaped lumen in a catheter device would be an obvious design consideration for one of ordinary skill in the art.

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In support of this assertion, Weaver et al disclose another flexible electrosurgical tool for an endoscope very much like the Rydell device. In particular, Weaver et al provide lumens in the flexible body for the passage of various instruments and devices, including electrode leads. Of particular note, Weaver et al teach of the well-known use of variously shaped lumens for providing advantageous characteristics, such as diminished cross sectional area, for the flexible member. Figures 12 and 12a of the Weaver et al device show the use of circular-shaped lumens, and Figures 19-24 show various other configurations including combinations of circular and semi-circular shaped lumens to maximize lumen surface area. In column 10, lines 18-35, Weaver et al specifically disclose that the various alternative lumen shapes are deemed obvious alternatives.

To have provided the Ouchi flexible tube with two channels for providing the individual conductive wires and obviating the need for insulation coatings on the individual wires would have been an obvious alternative arrangement for one of ordinary skill in the art, particularly since Rydell teach that providing two channels in an insulating tube is a known alternative to insulated wires being passed through a single lumen in an insulating tube. To have further provided the two channels as two circular lumens to more fittingly receive the leads would have been an obvious design consideration for one of ordinary skill in the art in view of the Weaver et al patent which teaches that such alternative lumen shapes are generally well known and obvious alternatives.

Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slater et al (5,482,054), Rydell (5,035,696) and Weaver et al (5,536,248) as applied to the above claims, and further in view of the teaching of Sutton et al (5,762,613).

Slater et al provides a clevis attachment at the distal end of the device to operate the jaws, but fails to specifically disclose a pair of pins, each pin supporting a separate jaw as recited in claims 8-10. Rather, Slater et al provides a single insulative pin (28) upon which both jaws are connected.

Sutton et al disclose a similar device that includes a flexible tubular member (22) with a pair of control wires extending therethrough and connected to jaws (80,81) of an end effector. In particular, Sutton et al teach that the distal end of the device may include a clevis having two separate pins (72,73) with each jaw member connected to a separate pin to allow individual actuation of the jaw members.

To have provided the Slater et al device, as modified by the prior art teachings, with a dual pin clevis construction to allow for the individual actuation of the jaw members would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Sutton et al (5,762,613).

Conclusion

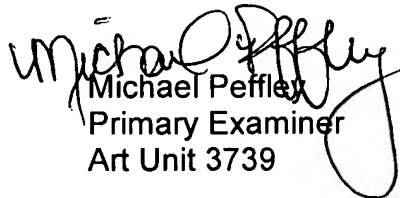
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lind (5,820,630) and Asano et al (5,908,437) disclose alternative flexible biopsy jaw devices including a pair of wires extending through a tube, and Parins et al (5,603,711) discloses another bipolar biopsy device that includes a pair of wires extending through the tube.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Peffley
Primary Examiner
Art Unit 3739

mp
March 2, 2006